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ELF ATOCHEM NORTH AMERICA, INC.
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King of Prussia, PA 19406-0018

Tel: 215-337-6500

8EHQ-0993-12436

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September 13, 1993

FEDERAL EXPRESS
RETURN RECEIPT REQUESTED

Document Processing Center (TS-790)
Office of Toxic Substances
Environmental Protection Agency
401 M St. S.W.
Washington, D.C. 20460
Attn: Section 8(e) Coordinator

Subject: TSCA Section 8(e) Submission

Dear Sir/Madam:

Elf Atochem North America Inc. is submitting the attached study to the Environmental Protection Agency (EPA) pursuant to Toxic Substances Control Act (TSCA) Section 8(e). This study does not involve effects in humans.

The enclosed study summary recently came into our possession via our parent company in France and provides information on MADQUAT BZ 75. MADQUAT BZ 75 is N,N-Dimethyl-N-[2-[(2-methyl-1-oxy-2-propenyl)oxy]ethyl] benzenemethanaminum chloride (CAS No. 46917-07-1). This product is manufactured for research and development purposes by Elf Atochem for use as a monomer in polymer synthesis.

Nothing in this letter or the enclosed study summary is considered confidential business information of Elf Atochem.

The title of the enclosed study summary report is MADQUAT BZ 75 Skin Sensitization Test in Guinea Pigs. The following is a summary of the adverse effects observed in the skin sensitization test.

MADQUAT BZ 75 was tested for potential to produce allergic skin reaction by intradermal injection and skin application to guinea pigs using a modified Magnusson and Klingman method. The test material produced a 75% (15/20) sensitization rate and was classified as a strong sensitizer.

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10-1-93

6 pgs.

Elf Atochem has not previously filed any 8(e) notices on the subject material.
A premanufacture notification was previously filed by Elf Atochem and assigned case number P93-1412, but was found to be on the Confidential TSCA Inventory.

Results from the study summary report are being included in the current Elf Atochem Material Safety Data Sheet for MADQUAT BZ 75.

A copy of the full study report will be submitted to the Agency as soon as it becomes available. Further questions regarding this submission may be directed to me at (215) 337-6892.

Sincerely,

C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosure

M-1187

MADQUAT BZ 75

SKIN SENSITIZATION TEST

IN GUINEA-PIGS

Addressee

Mr. J.F. Régnier
Atochem S.A.
Groupe Elf-Aquitaine
La Défense 10, Cédex 42
92091 Paris-la-Défense
France

Date: 5.6.92

SUMMARY

At the request of Atochem S.A., Paris-la-Défense, France, the sensitization potential of the test substance MADQUAT BZ 75 was evaluated in guinea-pigs by intradermal injection and cutaneous application, according to the maximization method of Magnusson and Kligman (1), the O.E.C.D. Guideline No. 406 and the Principles of Good Laboratory Practice (O.E.C.D., 12th May 1981).

Methods

Thirty guinea-pigs (15 males and 15 females) were allocated to 2 groups: a control group (5 males and 5 females) and a treated group (10 males and 10 females).

The sensitization potential of the test substance was evaluated after a 10-day induction period during which the animals were treated with the vehicle (control group) or the test substance (treated group). On day 1, in presence of Freund's adjuvant 0.1 ml of the test substance was administered by intradermal route at a concentration of 1% in NaCl at 0.9%. On day 8, 0.5 ml of the test substance in its original form was applied by cutaneous route. After a period of 12 days without treatment, a challenge cutaneous application of 0.5 ml of the vehicle (left flank) and 0.5 ml of the test substance in its original form (right flank) were then performed on all animals. The substances were prepared on a dry compress, then applied to the skin and held in place for 24 hours by means of an occlusive dressing. The cutaneous reactions were then evaluated at the challenge application site, 24 and 48 hours after removal of the dressing.

After the final scoring period, the animals were sacrificed and cutaneous samples were taken from the challenge application sites in all animals. No histological examination was performed on the cutaneous samples.

Reference

(1) **Magnusson, B.; Kligman, A.M.:** The identification of contact allergens by animal assay. The guinea pig maximization test. J. Invest. Derm. 52: 268-276 (1969).

Results

No clinical signs were observed and no deaths occurred throughout the study.

After the challenge cutaneous application of the test substance, no cutaneous reactions in the control group and positive cutaneous reactions in the treated group were observed. The positive reactions consisted of a well-defined or moderate to severe erythema after 48 hours accompanied by a dryness of the skin in 10/10 males and in 5/10 females. The cutaneous reactions observed in 5/10 females were slight (erythema, scores of 1 or 2 after 24 hours and of 0 or 1 after 48 hours).

Conclusion

The test substance MADQUAT BZ 75 induced cutaneous reactions as a result of a sensitization process in 75% (15 out of 20) guinea-pigs. The allergenicity level of the test substance MADQUAT BZ 75 was **IV "Strong"** in guinea-pigs.

La Defense 10, cedex 42
92091 Paris-la-Défense
FRANCE

TEST ARTICLE ANALYSIS

METHACRYLOXYETHYLDIMETHYLBENZYL AMMONIUM CHLORIDE
(MADQUAT BZ 75)
Batch OP 749/90

ASPECT		C.L.
VISCOSITE (25°C)	Cps	n.d.
COLORATION	APHA	15
EAU	%	25,3
AMA	%	0,175
MADAME	%	0,066
EMHQ	ppm	885
POLYMERES	ppm	Néant
pH		5,8
pH 50/50		4,7
CHLORURE DE METHYLE	ppm	2
TOLUENE	ppm	3
Σ NI	ppm	58
CHLORO TOLUENE	ppm	308
CHLORO TOLUENE	ppm	147
Σ NI	ppm	78
CHLORURE DE BENZYLE	ppm	2
ALCOOL BENZYLIQUE	ppm	67
NI	ppm	20
CHLORURE DE BENZYLIDENE OU DICHLORO TOLUENE	ppm	106
NI	ppm	15
ACRYLATE DE BENZYLE	ppm	4
METHACRYLATE DE BENZYLE	ppm	96

06 DEC. 1991

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

C.H. Farr
Manager, Product Safety and Toxicology
Elf Altochem North America, Inc.
900 First Avenue, P.O. Box 1536
King of Prussia, Pennsylvania 19406-0018

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

JAN 18 1994

This letter formally acknowledges EPA's receipt of information submitted by your organization under Section 8(e), the "substantial risk" information reporting provision of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA Section 8(e) Document Control Number (i.e., 8EHQ-0000-0000 Init.) assigned by EPA to your submission(s). Please refer to this cited number when submitting follow-up or supplemental information.

Please note that all submitted correspondence will be placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA Section 8(e) policy statement (43 FR 11110, March 16, 1978).

Confidential submissions submitted pursuant to the TSCA Section 8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims, because substantiation of CBI claims is required at the same time the 8(e) CAP is submitted to EPA. (If not done so already, please ensure that this information is provided to the Agency). When substantiating any/all claims, answer the questions detailed in the following attachment.

For NON-CAP submissions, any confidentiality claims should be supported by submission of information as described in the attachment(s).

12430 A

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TSCATS DATA:
submission # 8EHQ-0993-12430 SEQ A

TYPE (INT) SUPP FLWP

SUBMITTER NAME: ELF Atochem North America, Inc.

SUB. DATE: 09/13/93 OTS DATE: 09/17/93 CSRAD DATE: 10/01/93

CHEMICAL NAME: MADQUAT B275

CAS # 46917-07-1

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0509) REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/USERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

INFORMATION TYPE:		P	F	C
201	ONCO (HUMAN)	01	02	04
202	ONCO (ANIMAL)	01	02	04
203	CELL TRANS (IN VITRO)	01	02	04
204	MUTA (IN VITRO)	01	02	04
205	MUTA (IN VIVO)	01	02	04
206	REPRO/TERATO (HUMAN)	01	02	04
207	REPRO/TERATO (ANIMAL)	01	02	04
208	NEURO (HUMAN)	01	02	04
209	NEURO (ANIMAL)	01	02	04
210	ACUTE TOX. (HUMAN)	01	02	04
211	CHR. TOX. (HUMAN)	01	02	04
212	ACUTE TOX. (ANIMAL)	01	02	04
213	SUB ACUTE TOX (ANIMAL)	01	02	04
214	SUB CHRONIC TOX (ANIMAL)	01	02	04
215	CHRONIC TOX (ANIMAL)	01	02	04

INFORMATION TYPE:		P	F	C
0216	EPI/CLIN	01	02	04
0217	HUMAN EXPOS (PROD CONTAM)	01	02	04
0218	HUMAN EXPOS (ACCIDENTAL)	01	02	04
0219	HUMAN EXPOS (MONITORING)	01	02	04
0220	ECO/AQUA TOX	01	02	04
0221	ENV. OCCC/REL/FATE	01	02	04
0222	EMER INCI OF ENV CONTAM	01	02	04
0223	RESPONSE REQST DELAY	01	02	04
(0224)	PROD/COMP/CHEM ID	01	02	04
0225	REPORTING RATIONALE	01	02	04
0226	CONFIDENTIAL	01	02	04
0227	ALLERG (HUMAN)	01	02	04
(0228)	ALLERG (ANIMAL)	01	02	04
0239	METAB/PHARMACO (ANIMAL)	01	02	04
0240	METAB/PHARMACO (HUMAN)	01	02	04

INFORMATION TYPE:		P	F	C
0241	IMMUNO (ANIMAL)	01	02	04
0242	IMMUNO (HUMAN)	01	02	04
0243	CHEM/PHYS PROP	01	02	04
0244	CLASTO (IN VITRO)	01	02	04
0245	CLASTO (ANIMAL)	01	02	04
0246	CLASTO (HUMAN)	01	02	04
0247	DNA DAM/REPAIR	01	02	04
0248	PROD/USE/PROC	01	02	04
(0257)	MSDS	01	02	04
0299	OTHER	01	02	04

TRIAGE DATA:

NON-CBI INVENTORY:
(YES (CO...NU...)
NO (DROP)
DETERMINE

ONGOING REVIEW:
YES (DROP/REFER)
NO (CONTINUE)
REFER:

SPECIES: GP

TOXICOLOGICAL CONCERN:
LOW
(MED) dermal sensitization
HIGH

USE: R:D, monomer in polymer synthesis

PRODUCTION:

COMMENTS: Non-CAP
Skin sensitization in guinea pigs is medium because the test material sensitized 15/20 (75%) of the guinea pigs during a modified Magnusson + Kligman test.

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CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 0993-12430 SEQ B

TYPE: INT (SUPP) FLWP

SUBMITTER NAME: Atochem North America, Inc.

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 09/27/93 OTS DATE: 09/29/93 CSRAD DATE: 10/25/93

CHEMICAL NAME: MADQUAT BZ 75

CAS# 46917-07-1

INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04	0216	EPI/CLIN	01 02 04	0241	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242	IMMUNO (HUMAN)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04	0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04	(0243)	CHEM/PHYS PROP	01 02 04
0204	MUTA (IN VITRO)	01 02 04	0219	HUMAN EXPOS (MONITORING)	01 02 04	0244	CLASTO (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04	0220	ECO/AQUA TOX	01 02 04	0245	CLASTO (ANIMAL)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04	0221	ENV. OCCC/REL/FATE	01 02 04	0246	CLASTO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04	0222	EMER INCI OF ENV CONTAM	01 02 04	0247	DNA DAM/REPAIR	01 02 04
0208	NEURO (HUMAN)	01 02 04	0223	RESPONSE REQEST DELAY	01 02 04	(0248)	PROD/USE/PROC	01 02 04
0209	NEURO (ANIMAL)	01 02 04	(0224)	PROD/COMP/CHEM ID	01 02 04	0251	MSDS	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04	0225	REPORTING RATIONALE	01 02 04	0299	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04	0226	CONFIDENTIAL	01 02 04			
0212	ACUTE TOX. (ANIMAL)	01 02 04	0227	ALLERG (HUMAN)	01 02 04			
0213	SUB ACUTE TOX (ANIMAL)	01 02 04	(0228)	ALLERG (ANIMAL)	01 (02) 04			
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04	0239	METAB/PHARMACO (ANIMAL)	01 02 04			
0215	CHRONIC TOX (ANIMAL)	01 02 04	0240	METAB/PHARMACO (HUMAN)	01 02 04			

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	(YES (CONTINUE))	YES (DROP/REFER)	GP	LOW	R&D purposes as a monomer in polymer synthesis	
	NO (DROP)	NO (CONTINUE)		(MED) dermal sensitization		
	DETERMINE	REFER		HIGH		

COMMENTS: [illegible]
Dermal sensitization (Magnusson and Kligman test). No clinical signs of toxicity or deaths were observed in 20 guinea pigs in this guinea pig [illegible]. After challenge, well-defined and moderate-to-severe erythema and dry skin were observed in 10/10 males and 5/10 females. Positive reactions were therefore seen in 75% (15/20) of the treated animals.